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cyclomedica technegas

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# 2023 REVENUE UPDATE & USA MARKET EXPANSION OF TECHNEGAS®

**Dear Shareholders** 

Cyclopharm (ASX:CYC) is pleased to share the latest developments and progress at Cyclopharm, focusing on our strong 2023 revenue performance and the exciting developments in the United States market for our innovative product, Technegas, a nuclear medicine lung ventilation imaging agent.

## **2023 REVENUE UPDATE**

Our unaudited revenues for the full year 2023 reached an impressive \$28.9 million, marking a substantial 14% increase over the prior year. A more comprehensive breakdown of our revenue analysis will be provided when our full-year accounts are released later this month. This outstanding growth is a testament to the continued demand and acceptance of Technegas globally and our expanding offering and distribution of third-party products.

### UNITED STATES UPDATE

Following the United States Food and Drug Administration (USFDA) approval of Technegas on October 3, 2023, Cyclopharm has been diligently executing its plan for Technegas in the United States.

The ongoing launch strategy has to date yielded over 80 issued contracts covering more than 280 individual institutions across both the private and government sectors. Of those contracts issued to date, 6 contracts have either been executed or waiting final signatures with a further 3 contracts nearing final draft stage.

Cyclopharm's plan has to date encompassed three strategic phases, each designed to expedite penetration into the market.

- Phase One: Initiated with the nine sites involved in our recent clinical trial and specific clinicians engaged in the USFDA New Drug Application.
- Phase Two: Includes clinicians, scientists, and frontline workers who supported Technegas' approval during the challenging times of the COVID-19 pandemic.
- Phase Three: Commenced on January 26, 2024, targeting the over 400 expressions of interest received during our NDA process.

The introduction of Technegas in the US market differs from other products in that significant clinical demand already exists. Whilst clinical support is the first and most important step in the introduction of any new pharmaceutical or medical device, once clinical support is achieved, there are several sequential steps that must occur prior to clinical implementation. These approval steps include submissions to hospital administrators; to Pharmacy and Therapeutic Committees; to Formulary Committees; to Procurement; to Accounting; and to Legal departments. For radiopharmaceuticals, there are also the added signoffs by Radiation Safety Officers, Biomedical Engineers and Facility

Managers. Assisting our nuclear medicine customers in their path to signoff is principally what the sales process is for Technegas in the US.

## **REGULATORY MILESTONE**

On January 30, 2024, our US subsidiary, Cyclomedica USA LLC, was granted its Pharmaceutical Wholesale License by the Georgia Drugs and Narcotics Agency (GDNA) which formally empowers us to independently commence importation and distribution of Technegas products in the United States. Our first employee in the USA, Mr. Ken Duke, RPh., a nuclear pharmacist and former faculty member from the University of Georgia College of Pharmacy, played a pivotal role in securing the license.

### **REVENUE GENERATION**

We are now scheduling the first clinical installations during February and revenues will follow with each installation.

As previously advised, Technegas revenues include:

- a one-off charge of \$7,000 USD for installation and training
- a separate ongoing \$7,000 per annum technology fee invoiced at the time of installation
- a 50-patient box of patient consumables valued at \$11,250 that is required to initiate patient imaging.

The company will continue to own the Technegas system with ongoing revenues generated per site from the annual technology access fee and patient volumes.

### **BUILDING THE TEAM**

As part of the roll out of Technegas in the USA, we have initiated the onboarding process for new team members to include Service Engineers, Application Specialists, and our Customer Success Manager. Notably, our Customer Success Manager will be based at our new US Headquarters in Atlanta, Georgia.

### Dr. Tina Buehner, PhD to Join as Director of Medical Affairs

As part of enhancing our leadership team, we are pleased to announce the appointment of Dr. Tina Buehner as the Director of Clinical Affairs of Cyclomedica USA, LLC, a wholly owned subsidiary of Cyclopharm Limited. Dr. Buehner brings an extensive 25-year career and a distinguished background in the field of Nuclear Medicine and Molecular Imaging.

Tina began her career as a staff nuclear medicine technologist and clinical educator in Chicago, Illinois, USA. She holds board certifications in nuclear medicine technology, computed tomography, and radiation safety from the Nuclear Medicine Technology Certification Board (NMTCB) and the American Registry of Radiologic Technologists (ARRT). Her academic experience culminated in a Doctor of Health Sciences degree with an elective focus in Medical Physics from Rush University in Chicago, Illinois.

Actively engaged in various professional organizations, Tina has held leadership positions and committee chair appointments within the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the Society of Nuclear Medicine Technologist Section (SNMMI-TS), and the Nuclear Medicine Technology Certification Board (NMTCB). She was honored with SNMMI-TS Fellowship in 2015 and has recently held the position of President of the SNMMI-TS.

Managing Director and CEO Mr James McBrayer said, "Dr. Buehner's appointment as Director of Clinical Affairs at Cyclomedica, LLC, marks a significant milestone as we enter the US market. Her wealth of experience, leadership acumen, strong ties with clinicians, technologists, and scientists throughout the USA along with her dedication to advancing nuclear medicine aligns seamlessly with

Company's mission. We are confident that our clinical affairs initiatives in the USA and around the world will benefit tremendously from her experience."

### TECHNEGAS LAUNCH AT THE SNMMI MID-WINTER MEETING

Managing Director and CEO, Mr. James McBrayer, stated, "We have been extremely pleased with the enthusiasm expressed by the nuclear medicine community in the US since approval. We had the opportunity to witness this support at scale this past weekend at the SNMMI mid-winter meeting. This was the first meeting held since Technegas was approved. We were particularly pleased to see on the program a session that substantially featured the clinical and operational benefits of Technegas."

The meeting was an outstanding success measured by the several requests for proposals received and the face-to-face interaction with those that we have already been working with to implement Technegas into their practices.

### IN CLOSING

2023 was perhaps one of the most important years for Cyclopharm. We achieved a long sought after goal of gaining USFDA approval for our manufacturing site in Australia followed by approval to market Technegas in the USA, the largest healthcare market in the world.

Throughout these milestones we achieved another record year of revenues from the now 65 countries where are products and services are delivered.

We look forward to providing shareholders our full accounts later this month and regular USA commercialisation updates.

- ENDS -

This ASX announcement was approved and authorised for release by James McBrayer, Managing Director, CEO and Company Secretary.

### For more information, please contact:

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#### Cyclopharm Limited

Cyclopharm is an ASX Listed radiopharmaceutical company servicing the global medical community. The Company's mission is to provide nuclear medicine and other clinicians with the ability to improve patient care outcomes. Cyclopharm achieves this objective primarily through the provision of its core radiopharmaceutical product, Technegas<sup>®</sup> used in functional lung ventilation imaging.

#### Technegas<sup>®</sup>

The Technegas<sup>®</sup> technology is a structured ultra-fine dispersion of radioactive labelled carbon, produced by using dried Technetium-99m in a carbon crucible, micro furnaced for a few seconds at around 2,700° C. The resultant gas like substance is inhaled by the patient (lung ventilation) via a breathing apparatus, which then allows multiple views and tomography imaging under a gamma or single photon emission computed tomography (SPECT) camera for evaluating functional ventilation imaging. Historically used in the diagnosis of pulmonary embolism, Technegas<sup>®</sup>, together with advancements in complementary technology to multimodality imaging and analytical software, is being used in other disease states to include COPD, asthma, pulmonary hypertension, Long COVID and certain interventional applications to include lobectomies in lung cancer and lung volume reduction surgery.